

To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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1.0 Description of the Procedure, Product, or Service

This policy addresses three transplantation services:

- a. a simultaneous pancreas and kidney transplant;
- b. a pancreas transplant some time following a kidney transplant; and
- c. a pancreas transplant alone.

Transplantation of a normal pancreas is a treatment method for beneficiaries with Type 1 diabetes mellitus. Pancreas transplantation can restore glucose control and is intended to prevent, halt, or reverse the secondary complications of Type I diabetes mellitus. Achievement of insulin independence with resultant decreased morbidity and increased quality of life is the primary health outcome. While pancreas transplantation is generally not considered a life-saving treatment, in a small subset of patients who experience life-threatening complications from Type I diabetes, pancreas transplantation could be considered life saving.

Pancreas transplantation occurs in several different clinical situations, including:

- a. a Type I diabetic beneficiary with renal failure who may receive a cadaveric simultaneous pancreas/kidney transplant (SPK);
- b. a Type I diabetic beneficiary who may receive a cadaveric or living-related pancreas after a kidney transplantation (pancreas after kidney. i.e., PAK); or
- c. a non-uremic Type I diabetic beneficiary with specific severely disabling and potentially life-threatening diabetic problems who may receive a pancreas transplant alone (PTA).

The experience with SPK transplant is more extensive than that of other transplant options.

The approach to retransplantation varies according to the cause of failure. Surgical technical complications such as venous thrombosis are the leading cause of pancreatic graft loss among diabetic patients. Graft loss from chronic rejection may result in sensitization, increasing both the difficulty of finding a cross-matched donor and the risk of rejection of a subsequent transplant.

1.1 Definitions

None Apply.

2.0 Eligible Beneficiaries

2.1 Provisions

2.1.1 General

(The term "General" found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:

1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.
 - c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.
 - d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term "Specific" found throughout this policy only applies to this policy)

- a. **Medicaid**
None Apply.
- b. **NCHC**
None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.

2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <https://medicaid.ncdhhs.gov/>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;

- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

- a. Medicaid and NCHC shall cover pancreas transplantation when the beneficiary meets any one of the following criteria:
 - 1. a **Combined Pancreas-Kidney transplant** when medically necessary in beneficiaries with **Type I diabetes mellitus (DM)** with uremia;
 - 2. a **Pancreas transplant after a prior kidney transplant** when medically necessary in beneficiaries with insulin-dependent diabetes mellitus (Type I DM);
 - 3. a **Pancreas transplant alone** when medically necessary in beneficiaries with severely disabling and potentially life-threatening complications due to hypoglycemic unawareness and labile insulin-dependent diabetes (Type I DM) that persists in spite of optimal medical management; or
 - 4. a **Pancreas retransplant after a failed primary pancreas transplant** when medically necessary for all three types of pancreas transplants (i.e., combined pancreas-kidney transplant, pancreas transplant after a prior kidney transplant, and pancreas transplant alone);

AND

- 5. a beneficiary who meets the eligibility criteria for the transplant center performing the procedure; and
- 6. a beneficiary and caregiver who are willing and capable of following the post transplant treatment plan.

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- b. Medicaid and NCHC shall cover a beneficiary for any type of pancreas transplantation when the beneficiary meets the specific criteria listed in **Subsection 3.2.1** and all of the following criteria:
 - 1. Adequate cardiopulmonary status;
 - 2. Absence of significant infection that could be exacerbated by immunosuppressive therapy (e.g., chronic active viral hepatitis B, hepatitis C and human immunodeficiency virus (HIV)), and
 - 3. No active, potentially life-threatening, malignancy;
 - 4. Documentation of compliance with medical management; and
 - 5. Absence of uncontrolled HIV infection. HIV infection is considered controlled when the following criteria are met:
 - A. Cluster Differentiation 4 (CD4) count greater than 200 cells mm⁻³ for more than 6 months;
 - B. HIV-1 Ribonucleic acid (RNA) undetectable;
 - C. the beneficiary is stable on anti-retroviral therapy more than 3 months; and
 - D. the beneficiary has no other complications from acquired human immunodeficiency (AIDS) (e.g., opportunistic infection,

including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).

- c. Candidates for **pancreas transplantation alone** shall additionally meet one of the following severities of illness criteria:
 1. documentation of severe hypoglycemia unawareness as evidence by chart notes or emergency room visits; or
 2. documentation of potentially life-threatening labile diabetes as evidenced by chart notes or hospitalization for diabetic ketoacidosis.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Non-Covered Criteria

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

Medicaid and NCHC shall not cover pancreas transplantation for a beneficiary who does not meet the criteria and guidelines listed in **Section 3.0** and who has any one of the following:

- a. poor physiologic age;
- b. significant emotional problems that may impair the beneficiary's ability to adhere to follow up;
- c. current tobacco use (impairs wound and microvascular healing);
- d. other major organ system disease or infection, including major vascular disease;
- e. morbid obesity (defined as BMI greater than or equal to 40);
- f. uncontrolled HIV-positive beneficiaries
- g. organs sold rather than donated to a beneficiary; or
- h. artificial organs or human organ transplant service for which the cost is covered or funded by governmental, foundation, or charitable grants.

4.2.2 Psychosocial History

Medicaid and NCHC shall not cover pancreas transplantation when the beneficiary's psychosocial history limits the beneficiary's ability to comply with pre- and post-transplant medical care.

4.2.3 Medical Compliance

Medicaid and NCHC shall not cover pancreas transplantation when there is a current beneficiary or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

4.2.4 Substance Use

Medicaid and NCHC shall not cover pancreas transplantation

- a. when the beneficiary has an active substance use; or
- b. for beneficiaries with a recent history of substance use, where there is no documentation of
 1. a completed substance abuse or therapy program; plus
 2. six months of negative sequential random drug screens.

4.2.5 Medicaid Additional Criteria Not Covered

None Apply.

4.2.6 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 1. No services for long-term care.
 2. No nonemergency medical transportation.
 3. No EPSDT.
 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Medicaid and NCHC shall require prior approval for pancreas transplant. The provider shall obtain prior approval before rendering pancreas transplant.

All applicable N.C. Medicaid and NCHC policies and procedures must be followed in addition to the ones listed in this policy.

Only those beneficiaries accepted for transplantation by a transplantation center and eligible for transplant listing shall be considered for prior approval. Guidelines must be followed for transplant network or consortiums, if available.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

- a. the prior approval request; and
- b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.2.2 Specific

The provider(s) shall submit the following to the NC Medicaid transplant nurse consultant:

- a. Letter of medical necessity **signed by the attending transplant physician**, requesting transplant, summarizing the clinical history, social history and the transplant evaluation;
- b. All health care records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy including:
 1. Lab results (less than three months old) to include Complete Blood Count (CBC), complete electrolytes, liver enzymes, Prothrombin Time (PT), International Normalized Ratio (INR), glucose and A1C (Glycated Hemoglobin if Type I or Type II diabetic), and blood type;
 2. Baseline drug, alcohol, and nicotine/cotinine screenings on all adult transplant candidates;
 3. Serologies to include Human Immunodeficiency Virus (HIV), Hepatitis, Rapid Plasma Reagin (RPR), Epstein-Barr Virus (EBV), Cytomegalovirus (CMV), Varicella, Rubella, Herpes Simplex Virus (HSV) I/II, and toxoplasmosis. (*Positive* serology results may be reported that are greater than three months old);
 4. Diagnostic studies (less than six months old) required in a complete packet include:
 - A. Cardiac: Echocardiogram, Electrocardiogram (ECG), and/or cardiac catheterization as appropriate for beneficiary's clinical status;
 - B. Pulmonary: Pulmonary Function Test if beneficiary has cardiac or pulmonary issues, or a history of smoking; and
 - C. Chest x-ray for all transplant candidates;
 5. Other diagnostic tests may be requested as appropriate;
 6. Beneficiary's height and weight
 7. Results of all diagnostic and procedure results (not more than six months old)
- c. Complete psychological and social evaluation to include:
 1. beneficiary's medical compliance;
 2. beneficiary's support network;
 3. post-transplant care plan, with identification of primary and secondary care providers; and
 4. history of mental health issues/substance use/legal issues
- d. Beneficiaries with a psychiatric history are required to have an evaluation by a psychiatrist with expertise in evaluating the specific psychiatric issues that relate to transplant candidates.

5.3 Additional Limitations or Requirements

Beneficiaries with a history of alcohol (ETOH)/substance use shall fulfill the following criteria:

- a. Actively using ETOH/substance within the past year
 1. These beneficiaries shall have six months of counseling (at least twice per month) provided by a substance abuse provider.
 2. Shall have monthly toxicology/ETOH screens, continuing these screens monthly until listed; and
 3. Shall have toxicology/ETOH screens as needed (PRN).
- b. Clean/sober up to 2 years
 1. These beneficiaries shall have a counseling consult and the counselor will decide if the beneficiary requires continued recidivism counseling. Medicaid will accept the counselor's recommendations;
 2. These beneficiaries shall have ONE toxicology/ETOH screen during their evaluation; and
 3. Shall have toxicology/ETOH screens PRN.
- c. Clean/sober for greater than 2 years
 1. No counseling is necessary;
 2. Beneficiary shall have one toxicology/ETOH screen during evaluation; and
 3. Beneficiary shall have toxicology/ETOH screens PRN

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- c. meet Medicaid or NCHC qualifications for participation;
- d. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- e. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2 .1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).
- c. FDA approved procedures, products, and devices for implantation must be utilized for pancreas transplantation.
- d. A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the beneficiary's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

Revision Information:

Date	Section Revised	Change
07/01/2005	Throughout	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
09/01/2005	Section 2.2	The special provision related to EPSDT was revised.
12/01/2005	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/01/2006	Sections 2.2	The special provision related to EPSDT was revised.
12/01/2006	Sections 3.0 and 4.0	A note regarding EPSDT was added to these sections.
05/01/2007	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for beneficiaries under 21 years of age.
05/01/2007	Attachment A	Added the UB-04 as an accepted claims
07/01/2010	Throughout	Session Law 2009-451, Section 10.31(a) Transition of NC Health Choice Program administrative oversight from the State Health Plan to the Division of Medical Assistance (DMA) in the NC Department of Health and Human Services.
12/01/2011	Throughout	Policy was updated to include coverage criteria and requirements to meet current community standards of practice.
12/1/2011	Throughout	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 11B-7 Session Law 2011-145, § 10.41.(b)
03/12/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
08/01/2012	Subsection 5.3	Prior authorization requirements for recipients with ETOH/substance abuse issues was added.
08/01/2012	Throughout	Replaced "recipient" with "beneficiary."
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and Attachments	Updated policy template language.
01/06/2020	Table of Contents	Updated policy template language, "To all

Date	Section Revised	Change
		beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.”
01/06/2020	Attachment A	Added, “Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines”.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid’s clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

ICD-10 Procedure Codes
0FSG0ZZ
0FSG4ZZ
0FYG0Z0
0FYG0Z1

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

CPT Code(s)
48550
48554
48556
48160
50300
50320
50340
50360
50365

HCPCS Code
S2065

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

Acute inpatient hospital

G. Co-payments

For Medicaid refer to Medicaid State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

For NCHC refer to NCHC State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>

I. Billing for Donor Expenses

1. Billing for Donor Expenses for Medicaid Beneficiaries

Donor transplant-related medical expenses are billed on the Medicaid beneficiary's transplant claim using the beneficiary's Medicaid identification number.

Medicaid reimburses only for the actual donor's transplant-related medical expenses. Medicaid does not reimburse for unsuccessful donor searches.

2. Billing for Donor Expenses for NCHC Beneficiaries

Donor transplant-related medical expenses donors are billed on the NCHC beneficiary's transplant claim.

NCHC reimburses only for the actual donor's transplant-related medical expenses. NCHC does not reimburse for unsuccessful donor searches.

3. Cadaveric/Deceased Organ Donations

Donor transplant-related medical expenses (procuring, harvesting, and associated surgical and laboratory costs) for cadaveric/deceased organ donations are covered for a pancreas transplant if the transplant beneficiary has received prior approval for a cadaveric/deceased organ transplant procedure.

4. Living Organ Donations for a NCHC Beneficiary

Donor transplant-related medical expenses (procuring, harvesting, and associated surgical and laboratory costs) for living organ donations are covered for a pancreas transplant if the transplant beneficiary has received prior approval for a living organ transplant procedure. NCHC only covers reimbursement for the approved donor.

5. Living Organ Donations for a Medicaid Beneficiary

Donor transplant-related medical expenses (procuring, harvesting, and associated surgical and laboratory costs) for living organ donations are covered for a pancreas transplant if the transplant beneficiary has received prior approval for a living organ transplant procedure. Medicaid only covers reimbursement for the approved donor.